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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,544	03/17/2004	Kazuhisa Fukushima	042187	2323

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,544

Applicant(s)

FUKUSHIMA, KAZUHISA

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. As a result of the amendment of 08 November 2007, claims 1, 2, and 7 have been amended such that one is to "partition" a container into a first and second "area." Claim 1, 3, and 7 define "partition" as "a gel, a pillar array, or a porous filter." While each of these structures unquestionably has surface area, and occupies some volume, it is unclear how an "area" is to be construed as being equivalent to any of the aforementioned structures. Further, the metes and bounds of the term "area" are undeterminable with regard to claims 2 and 7, which do not recite any one or combination of structures.

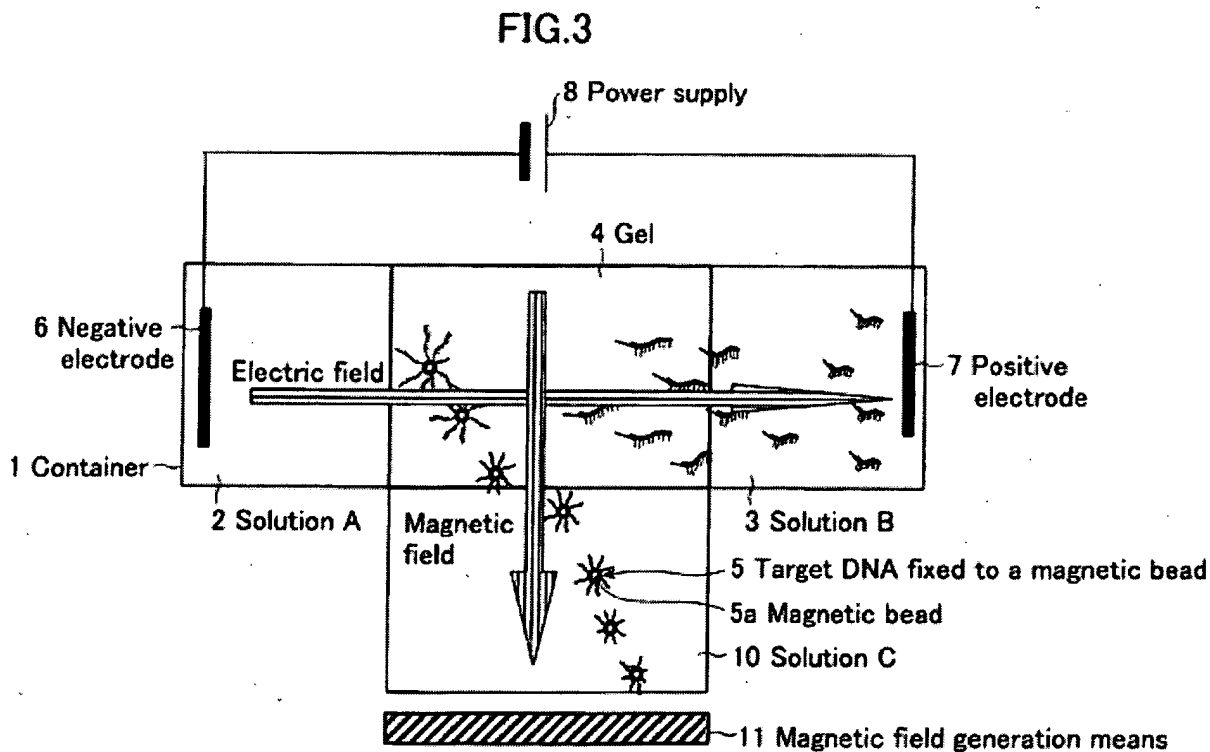
5. Claims 1, 2, and 7 are confusing as a result of the amendment to same. As presently worded, the method requires "partitioning a container into a first area." It is less than clear as to

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how one is to fashion an "area" when the "partition" is a pillar array, which is three-dimensional, while an area is two-dimensional.

6. If one is to fashion an "area," which is two-dimensional and thusly without volume, it is unclear how the biopolymer, which is three-dimensional, can be trapped in two-dimensional area, much less be caused to pass on to a second and/or third "area."

7. Acknowledgement is made of the figures depicting a device performing electrophoresis (see Figure 3, below) and that the surface of the device does occupy an "area," however, such illustrations do not identify "a gel, a pillar array, or a porous filter" as being a first or second area.



Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,635,045 (Alam).

10. For purposes of examination, the first, second and third “areas” have been construed as being simply different areas of a single gel, where there is no material difference in the composition of the gel exists and where the “partitioning” is virtual, not physical. Said expression has also been construed as encompassing “areas” that have a material difference and which may, or may not, have a physical barrier forming a physical “partition.”

11. Alam discloses a method of separating nucleic acids from other biopolymers. As disclosed therein, biopolymers are caused to migrate through a gel (applicant's partition/area) via electrophoretic force. A band of gel can be excised, and placed into a second “area,” wherein the biopolymer can be eluted and collected upon a membrane (applicant's porous filter), therein separating the target biopolymer (e.g., nucleic acids) from the buffer in the second “area”.

Response to argument

12. At page 7 of the response of 08 November 2007, argument is presented that Alam does not disclose the invention. In support of this position, argument is presented that the biopolymers of Alam are initially in wells, which is equivalent to biopolymers initially being in "the 'partition' of the claimed invention."

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13. The above argument has been fully considered and has not been found persuasive. It is noted that the claimed method does not prohibit the use of a well to initiate the process of electrophoresis. Clearly, the biopolymers of Alam do migrate through different regions of a gel. The different regions of the gel clearly meet the limitation of different areas, which is all that is required of claim 1. With Alam teaching the use of a gel, such also meets the limitation that the 'partition' can be a gel (see claims 1 and 3). Accordingly, and in the absence of convincing evidence to the contrary, claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,635,045 (Alam).

Claim Rejections - 35 USC § 102/103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-3 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,009,759 (Serwer et al.).

18. For purposes of examination, the term "partition" and "area" have been construed as encompassing not only pillar arrays, and filters but also gels.

19. Serwer et al., teaches developing and using both horizontal and vertical gels that have gradients of pore sizes. The differences in pore sizes may be abrupt or may be that found in a gradient, where an infinite number of degrees of separation can be developed. The myriad differences on pore sizes are deemed to meet the limitation of first, second, and third solutions. The portions of the gradient where the target biopolymers are slower to move, and where they may eventually be trapped, are deemed to meet the limitation of applicants first and second "partition" as the target biopolymers are removed/separated/portioned from the other biopolymers.

20. As disclosed by Serwer et al., a mixture of biopolymers (e.g., nucleic acids or proteins) may be added/introduced into a gel, and then subjected to an electrophoretic force.

21. Serwer, column 3, teaches that the gel can be dried. Such a showing is deemed to meet the limitation that the biopolymer is separated from the buffer.

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22. In view of the above remarks, the method of claims 1-3 is deemed disclosed, or in the alternative, rendered obvious over the disclosure of Serwer et al.

Response to argument

23. At page 8 of the response of 08 November 2007, argument is presented that "Serwer does not disclose or suggest a method in which a container is partitioned into two or three areas, and the target and other biopolymers are moved as recited, and then separated from the buffer."

24. The above argument has been fully considered and has not been found persuasive as the claimed method does not require the "partitioned container" to be physically separated. For purposes of examination, the limitation of a "partitioned container," is an "area" of a "gel;" see claim 1, lines 4 and 10. Serwer clearly teaches that the gel can comprise an infinite number of areas of a gel which have differing densities. Such differing densities of the "area"/"gel" are deemed to meet the requirement of a first, second, and third area.

25. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-3 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,009,759 (Serwer et al.).

26. Claims 7 and 8 remain rejected under 35 U.S.C. 103(a) as obvious over US Patent 5,635,045 (Alam) in view of US Patent Application Publication 2006/0127942 (Straume et al.).

27. Alam discloses a method of separating nucleic acids from other biopolymers. As disclosed therein, biopolymers are caused to migrate through a gel (applicant's partition/area) via electrophoretic force. A band of gel can be excised, and placed into a second "area," wherein the

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biopolymer can be eluted and collected upon a membrane (applicant's porous filter), therein separating the target biopolymer (e.g., nucleic acids) from the buffer in the second "area".

28. Alam has not been found to disclose the use of magnetic beads that are attached to biopolymers.

29. Straume et al., teach at length how magnetic beads can be coupled to any of a variety of biopolymers, including nucleic acids and proteins, and can be used to separate the bound biopolymer from other components in a sample.

30. Straume et al., page 12, disclose the use of beads in an electrophoretic medium, and that the beads can be coupled to nucleic acids.

31. Paragraph [0126] teaches that magnetic beads, when coupled to DNA, are able to move through a medium in response to electrophoretic force.

32. Straume et al., page 13, bridging to page 14, teaches separation of DNA from magnetic beads.

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods of Straume et al., with that of Alam, as both Alam and Straume et al., disclose isolation of biopolymers that have been caused to pass through various regions/chambers of an electrophoretic medium.

34. Said ordinary artisan would have been motivated to incorporate the method of Straume et al., into that of Alam as such would have allowed for the application of a magnetic force, and therein take advantage of the speedy movement of magnetic beads to a defined area, and therein enhance the isolation of a biopolymer from the electrophoretic buffer.

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35. As seen above, the elements disclosed by both Alam and Straume et al., are to function in the manner disclosed, and are to result in the same end point- the isolation of a biopolymer from a larger sample. In view of the detailed guidance, said ordinary artisan would have had a most reasonable expectation of success.

36. For the above reasons, and in the absence of convincing evidence to the contrary, claims 7 and 8 remain rejected under 35 U.S.C. 103(a) as obvious over US Patent 5,635,045 (Alam) in view of US Patent Application Publication 2006/0127942 (Straume et al.).

Response to argument

37. At page 9 of the response of 08 November 2007, argument is presented that Alam requires the DNA to be in wells while the biopolymer of the claimed method is initially in a first area of the partition, which can be a gel. This argument has not been found persuasive towards the withdrawal of the rejection as the well is clearly in the gel/area/partition. Further, the claimed method does not prohibit one of the three areas of the gel from being a well. Assuming *arguendo* that the claims were amended so to recite the limitation that the first area is not a well, such would not preclude additional method steps, such as those that would get the biopolymer into the gel in the first instance, something that the present method is silent on.

38. At page 9 of said response argument is presented that the magnetic beads of Straume have an electrical charge.

39. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection as the claims do not prohibit use of magnetic beads that have such a charge. It is further noted that Straume teaches that magnetically-responsive beads with a variety of surface charges are commercially available. It would have been obvious to one

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of ordinary skill in the art at the time the invention was made to have selected those beads that would have worked.

40. Attention is directed to the decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007)

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

41. It is further noted that prior art is not limited to the four corners of the documentary prior art being applied. Prior art includes both the specialized understanding of one of ordinary skill in the art, and the common understanding of the layman. It includes “background knowledge possessed by a person having ordinary skill in the art. . . [A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR* at 1396.

42. At page 9, bridging to page 10 of the response, argument is provided that there is no suggestion or motivation to combine. This argument has not been found persuasive as suggestion, teaching or motivation does not have to be explicit and “may be found in any number of sources, including common knowledge, the prior art as a whole or the nature of the problem itself” *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007) citing *Dystar Textilfarben GMBH v. C. H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

43. For the above reasons, and in the absence of convincing evidence to the contrary, claims 7 and 8 remain rejected under 35 U.S.C. 103(a) as obvious over US Patent 5,635,045 (Alam) in view of US Patent Application Publication 2006/0127942 (Straume et al.).

Conclusion

44. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

45. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

46. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner
Art Unit 1634

BLS